

What is claimed is:

1. A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
  - (a) a controlled release core comprising an antihyperglycemic drug and at least one pharmaceutically acceptable excipient; and
  - (b) an immediate release thiazolidinedione derivative containing component wherein not less than 85%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
2. The pharmaceutical dosage form as defined in claim 1 wherein not less than 90%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
3. The pharmaceutical dosage form as defined in claim 1 wherein not less than 95%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
4. The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
5. The pharmaceutical dosage form as defined in claim 1 wherein not less than 85%, of the thiazolidinedione is released from the dosage form within 40 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
6. The pharmaceutical dosage form as defined in claim 1 wherein not less than 90%, of the thiazolidinedione is released from the dosage form within 40 minutes when tested according to the United States Pharmacopeia (USP) 26,

with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

7. The pharmaceutical dosage form as defined in claim 1 wherein not less than 95%, of the thiazolidinedione is released from the dosage form within 40 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
8. The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the thiazolidinedione is released from the dosage form within 40 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
9. The pharmaceutical dosage form as defined in claim 1 wherein not less than 85%, of the thiazolidinedione is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
10. The pharmaceutical dosage form as defined in claim 1 wherein not less than 90%, of the thiazolidinedione is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
11. The pharmaceutical dosage form as defined in claim 1 wherein not less than 95%, of the thiazolidinedione is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
12. The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the thiazolidinedione is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
13. A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

- (a) a controlled release core comprising an antihyperglycemic drug and at least one pharmaceutically acceptable excipient; and
- (b) an immediate release thiazolidinedione derivative containing component wherein the total thiazolidinedione related compounds or impurities in the final dosage form are not more than 0.6 as determined by high performance liquid chromatography.
14. The pharmaceutical dosage form as defined in claim 13 wherein the total thiazolidinedione related compounds are not more than 0.5%.
15. The pharmaceutical dosage form as defined in claim 13 wherein the total thiazolidinedione related compounds are not more than 0.5%.
16. The pharmaceutical dosage form as defined in claim 13 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.25%.
17. The pharmaceutical dosage form as defined in claim 16 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.20%.
18. The pharmaceutical dosage form as defined in claim 17 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.10%.
19. The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.
20. The dosage form of claim 19 wherein the osmotic tablet comprises:
- (a) a core comprising:
- (i) 50-98% of said antihyperglycemic drug;
- (ii) 0.1-40% of a binding agent;
- (iii) 0-20% of an absorption enhancer; and
- (iv) 0-5% of a lubricant;
- (b) optionally a seal coat surrounding the core; and
- (c) a sustained release membrane comprising:
- (i) 50-99% of a polymer;
- (ii) 0-40% of a flux enhancer and
- (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the antihyperglycemic drug.

21. The dosage form of claim 1 wherein said antihyperglycemic drug is a biguanide.
22. The dosage form of claim 1 wherein said thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.
23. The dosage form of claim 1 wherein said core is substantially free from any gelling or expanding polymer.
24. The dosage form of claim 1 wherein said controlled release of said antihyperglycemic drug provides a T<sub>max</sub> of 8-12 hours.
25. The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a T<sub>max</sub> of 1-12 hours.
26. The dosage form of claim 25 wherein said release of the thiazolidinedione derivative provides a T<sub>max</sub> of 1-4 hours.
27. The dosage form of claim 13 wherein said controlled release core is an osmotic tablet.
28. The dosage form of claim 27 wherein the osmotic tablet comprises:
- (d) a core comprising;
    - (i) 50-98% of said antihyperglycemic drug;
    - (ii) 0.1-40% of a binding agent;
    - (iii) 0-20% of an absorption enhancer; and
    - (iv) 0-5% of a lubricant;
  - (e) optionally a seal coat surrounding the core; and
  - (f) a sustained release membrane comprising;
    - (iv) 50-99% of a polymer;
    - (v) 0-40% of a flux enhancer and
    - (vi) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the antihyperglycemic drug.
29. The dosage form of claim 13 wherein said antihyperglycemic drug is a biguanide.
30. The dosage form of claim 13 wherein said thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.

31. The dosage form of claim 13 wherein said core is substantially free from any gelling or expanding polymer.
32. The dosage form of claim 13 wherein said controlled release of said antihyperglycemic drug provides a Tmax of 8-12 hours.
- 5 33. The dosage form of claim 13 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
34. The dosage form of claim 33 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.